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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,001	12/13/2006	Matthias Augustin	P30391	1364
7055	7590	07/29/2010	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				DAVIS, DEBORAH A
ART UNIT		PAPER NUMBER		
		1655		
NOTIFICATION DATE			DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/588,001	AUGUSTIN ET AL.
	Examiner	Art Unit
	DEBORAH A. DAVIS	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 May 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 48-71 is/are pending in the application.
 4a) Of the above claim(s) 50-53, 55-59, 63 and 64 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 48-49, 54, 60-61, and 65-71 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4-7-10</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the following species: A. Administration to skin; B. Microbe-caused disease - microbe infected dermatose; C. Solution, spray, tincture, oil-in-water emulsion; water-in-oil emulsion; in the reply filed on 5-5-10 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden to examiner all of the species. This is not found persuasive because restriction is not based on a burdensome search alone but includes the criteria of patentable independent or distinct inventions. Further, the search for each invention is not co-extensive particularly with the other. A reference that anticipates one group may not necessarily anticipate or even make obvious the other. Please note that classification is illustrative only and do not represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issues US patents, but rather includes foreign patents and applications as well as literature searches. **The elected species are readable on claims 48-49, 54, 60-62, and 65-71. All other claims are hereby withdrawn as not reading on the elected species.**

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65 and 69-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 65 and 69 recites that the oil of coriander is in “pure form” which is vague because the metes and bounds of the claims is unclear. The examiner does not know if “pure form” means that the oil has been purified or if coriander is administered alone.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-49, 54, 60-62, and 65-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a microbe-caused disease of at least one skin condition disclosed in the instant claims, does not reasonably provide enablement for preventing a microbe-caused disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors regarding undue experimentation have been summarized in *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The State of the prior art;
- (6) The predictability or unpredictability of the art;
- (7) The breadth of the claims; and
- (8) The relative skill of those in the art

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instantly claimed invention is drawn to a method of treating or preventing a microbe-caused disease of at least one of skin, a mucous membrane and an oral cavity, wherein the method comprises an administration to a subject of an amount of oil of coriander which is effective for treating or preventing the microbe-caused disease

Breadth of the claims: The claims were given its broadest and reasonable interpretation that is consistent with applicant's specification.

Guidance of the Specification and Existence of Working Examples:

The specification describes a clinical screening study of coriander oil in healing and treating experiments in which it demonstrated efficacy against atopic eczema and nummular eczema. The coriander oil treatment also proved to be effective against tinea diseases as well as Candida interigo. However, the specification does not show any working examples of where the coriander oil prevented any of the microbe-caused diseases of the mucous membrane, oral cavity or the skin. Although the M.P.E.P. does not require working examples, there must be sufficient teaching in the specification to enable one of ordinary skill in the art to use the method as instantly claimed. The specification lacks such teaching and therefore the subject matter for "preventing" such microbe-caused diseases is not enabled. Thus, there has not been provided adequate guidance in the specification for accomplishing this process using the oil of coriander as claimed.

Amount of Experimentation Necessary:

The quantity of experimentation necessary to carry out the claimed invention is high, because the skilled artisan could not rely on the instant specification or the prior art to teach a method of administering the oil of coriander to *prevent* a microbe-caused disease. Therefore, in view of the nature of the invention, breadth of the claims and the lack of guidance in the specification as well as the amount of experimentation necessary, the skilled artisan would not be able to practice the invention. Therefore the instant claims are not considered to be fully enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-49, 54, 61-62, 65-69, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al UK Publication (GB 2 359 746).

A method of treating a microbe-caused disease of at least one of skin, a mucous membrane and an oral cavity, wherein the method comprises an administration to a subject of an amount of oil of coriander which is effective for treating the microbe-caused disease is apparently claimed.

The cited reference of Lilley et al. beneficially teaches the instant claims by disclosing a one or more of essential oils selected from coriander and others therein for the inhibition of pathogenic bacteria in the oral cavity that define such disorders as gingivitis, periodontal disease, dental caries and particularly disorders related to or caused by the activity of anaerobic bacteria (gram positive bacteria), which the examiner interprets of microbe-caused diseases, as claimed (page 3, lines 5-30, e.g.).

The oral cavity comprise of skin, teeth and gum. Therefore the oral cavity read on skin. The coriander oil can be suitable for administration to humans and animals in the form of chewing gum, dental floss, mouth rinses (i.e. solution), toothpaste and other dental vehicles (page 11, lines 13-15, e.g.), which would be the contact site for the skin oral cavity. Such oral preparations are applied by contacting the gums by rinsing the oral

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cavity for about 15-90 seconds, or in the case where lozenges, candy or chewing gum are used by sucking or chewing in the oral cavity at least once daily (page 26-31, e.g.).

This all includes topical treatment of the oral cavity. There coriander oil and be in combination with other oils such as peppermint, lemongrass and others therein which have an antibacterial effect (see page 3, lines 19-23, e.g.).

The reference of Lilley et al. does not expressly teach the active step of administrating coriander oil to a mammal.

However, the reference of Lilley does teach that the composition is in administrable forms and is useful for topical treatment of the oral cavity which includes the skin. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer coriander oil to a mammal based on the beneficial teachings provided by the reference of Lilley. The coriander oil comes in administrable forms for delivery to the oral cavity to treat gingivitis, periodontal disease, and other dental disorders. The adjustment of particular conventional working conditions (i.e. determining suitable concentrations coriander oil) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

Claims 60 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al as applied to claims 48-49, 54, 61-62, 65-69, and 71 above, and further in view of Gail B. Mahady (Thai Journal of Phytophrmacy Vol. 9(1) Jun. 2002, pages 50-62).

The teachings of Lilley have been set forth above but do not expressly teach the that the microbe-caused disease is associated with at least one of Methicillin-resistant Staphylococcus aureus and a multi-resistant pathogen.

However, the reference of Mahady beneficially teaches that the overuse of antibiotics has been linked to drug resistance in some pathogens such as methicillin-resistant Staphylococcus aureus and Mycobacterium tuberculosis in man. Mahady beneficially teaches that many essential oils of medicinal plants have antimicrobial activity against such pathogens. Essential oils from coriander and others disclosed therein were tested for their ability to inhibit bacterial growth in the pathogens such as staphylococcus aureus, Escherichia coli, Listeria monocytogenes, Aspergillus niger, pseudomonas aeruginosa and others therein listed (See pages 52, col. 1, Table 1, page 59, col. 1, and Table 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to consider the use of coriander oil to treat multi-resistant pathogens with the composition of Lilley because Mahady teaches that such pathogens can become multi-resistant to the over use of antibiotics and therefore need an alternative treatments as in essential oils that include coriander.

Response to Arguments

Claim Rejections - 35 USC § 112 arguments:

Applicant traverses this rejection based on the specification's definition of prophylaxis treatment is always mentioned with the term treatment. Applicant argues that preventive treatment defines an already healthy user in order to prevent said user from catching the disease or preventive treatment of a healthy user, but one who has a certain pre-disposition for the disease. These arguments has been fully considered but not found to be persuasive of error.

In response, if applicant is claiming the prophylaxis treatment of specific microbe-caused disease then these limitations should be put into the claims and have support in the specification. As it stands, applicant's claims as drafted read on preventing any and every microbe caused disease. Applicant does not have support for preventing any and all microbe-caused diseases. Neither does the prior art teaches or suggest that the oil of coriander when administered can prevent microbe-caused disease. Please note that the term "preventing" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such any and all microbe-caused disease (which clearly is not recognized in the medical art as being a totally preventable condition).

Therefore, this rejection is hereby maintained and made final.

Claim Rejections - 35 USC § 103 rejection:

Applicant argues that the reference of Lilley is drawn to antimicrobial effects of the oil of coriander containing compositions for inhibiting anaerobic bacteria in the oral cavity in cases of gingivitis, dental caries and periodontal disease. Applicant concludes that there is no suggestion of treating the skin or mucosa with respect to microbe-caused disease. Applicant directs the examiner's attention to a teaching of Lilley that discloses:

It has now been found that certain essential oils, which in earlier studies had previously demonstrated only weak antibacterial activity, are particularly potent in their antibacterial effect against species of bacteria which are strongly implicated in periodontal disease and/or malodour production. According to the present invention there is provided the use of an effective amount of one or more essential oils selected from coriander oil, cumin oil, dill weed oil, lemongrass oil and peppermint oil in the manufacture of a composition for the inhibition of pathogenic bacteria, particularly anaerobic bacteria, present in the oral cavity of humans and other mammals, the composition being suitable for oral administration.

The applicant concludes from this teaching that the reference of Lilley does not read on the oil of coriander useful in the treatment of the skin or mucosa. These arguments have been fully considered but not found to be persuasive of error.

In response, treatment of the oral cavity includes the skin. The oral cavity is made of skin, teeth and bone. Therefore using a composition that includes the oil of coriander in the various dental treating forms such as mouth rinses, toothpaste, and other topical treatments for the oral cavity would also include treating the skin of the oral

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cavity. Lilley teaches treating gingivitis of the gum, which is a microbe-caused disease. The gum includes the skin of the oral cavity, and therefore meets the limitation of the instant claims. With respect to applicant's argument that the preferable oil is curcumin is not found persuasive because Lilley teaches other embodiments where curcumin may be the preferred oil. In addition, the claims include the open language of comprising, therefore other oils and ingredients are not prohibited.

Applicant argues that the reference of Vail does not teach diseases which are caused my MRSA and thereby fails to sure the noted deficiencies of Lilley. This argument has been fully considered and found to be persuasive. The reference of Vail is hereby withdrawn. However, based on the newly applied reference of Mahady above, these arguments are considered to be moot. Mahady beneficially teaches that essential oils that include coriander are useful in treating multi-resistant pathogens.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
July 2010

/Christopher R. Tate/
Primary Examiner, Art Unit 1655